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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/695,562	10/24/2000	Dr. Max Schaldach	7040-5	1946

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 02/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/695,562

Applicant(s)

SCHALDACH ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. At this time, a restriction election has not been requested. However, should the examiner determine a burdensome search in the future, a restriction election may be required. The five disclosed inventions are:

- A. Stent having coating portions in a non-uniform arrangement (p3, lines 16-27).
- B. Stent having coating portions with varying spacing (p5, lines 14-24).
- C. Stent having coating portions with varying sizes (p5, line 26 – p6, line 2).
- D. Stent having coating portions in a pattern-like or grid-like pattern (p4 lines 20-33).
- E. Stent having coating portions arranged as a thickness gradient (p3-4).

All five inventions may be classified in class 623, subclass 1.15, 1.34, or 1.46.

### ***Information Disclosure Statement***

2. The information disclosure statement filed October 24, 2000 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because English translations were not provided for references AF-AI. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based

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on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

### ***Drawings***

3. The subject matter of this application admits of illustration by a drawing to facilitate understanding of the invention. Applicant is required to furnish a drawing under 37 CFR 1.81. No new matter may be introduced in the required drawing.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitations of claims 2-16 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Stent having discontinuous coating.

7. The disclosure is objected to because of the following informalities: grammatical and typographical errors too numerous to specify exist in the specification. Some examples include page 3, line 30, page 2, line 10, page 6, line 30, and page 7, line 1. Appropriate correction is required. *6 16* *8 18*

8. Applicant is requested to submit a modified specification containing proper section headers as provided in 37 CFR 1.77(b).

### ***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 2-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected because the limitation "irregular in respect of its thickness" is not clearly described. The term "its" may be interpreted as the coating or the stent.

Claim 4 is rejected because the phrase "interrupted in a grid-like pattern" does not clearly define the invention. A "grid-like pattern" is not clearly defined and it is not

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understood how the coating can be "interrupted" into a particular pattern, whether it be "grid-like" or other pattern.

Claims 8 and 10 are rejected because the limitation "mutual spacing" is not clearly understood.

Claim 13 is rejected because the phrase formed irregularly is unclear as to whether the coating is irregular or the manner in which the stent is coated is irregular.

Claims 3, 5-7, 9, 11, 12, and 14-16 are rejected for being dependent on rejected claims.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 2-7 and 11-14 rejected under 35 U.S.C. 102(b) as being anticipated by Callol et al. (EP 0824900).

Callol et al. discloses various non-uniform and uniform coatings for stents preventing interference between the coating and stent during radial expansion of the stent.

Regarding claims 2-4 and 13, a non-uniform or irregular grid-like pattern having locations with no coating is described in lines 1-11 of column 7 (one or more discontinuous bands).

Regarding claims 5-7 and 11-14, gold coating islands of round shape and equal size are disclosed in lines 1-11 of column 7 (dots) and column 5, line 38 to column 6, line 5.

12. Claims 2-11 and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Yan (US PN 5,843,172).

13. Regarding claims 2-4, 11, and 13, a biocompatible and irregularly formed grid-like surface coating having locations where the coating is missing completely is shown in figure 5.

14. Regarding claims 5-7 and 14, substantially round coating islands of equal size are shown in figure 10.

15. Regarding claims 8 and 15, figure 12 shows coating islands spaced farther apart where a greater degree of stretching or expansion occurs. More specifically, if the bottom layer (112) faces the vessel lumen and the upper layer (110) faces the vessel wall, the spacing between the coating islands outside of middle layer (108) have greater spacing than the spacing between the outermost coating islands (114). Furthermore, during radial expansion, the inner layer coating islands will experience greater stress concentrations than the outer layer coating islands.

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16. Regarding claims 9 and 16, figure 12 shows smaller coating islands where greater degrees of local stretching occur.

### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (US PN 5,843,172) in view of Callol et al. (EP 0824900).

19. Yan meets the limitations of claims 12, as described above, but lacks or does not expressly disclose the coating islands comprising gold. However, Callol et al. teaches the use of gold for a radiopaque coating because of its resistance to cracking during deployment (lines 51-58 of column 4). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the stent coating taught by Yan to include gold in order to reduce the possibility of cracking during deployment.

### ***Conclusion***

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM

February 21, 2002



Paul B. Prebitt  
Primary Examiner